Case Docket No.: SKLAR-21

Assistant Commissioner For Patents
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is the patent application of:

Inventor: Joseph H. Sklar .
For: LIGAMENT SHIM .
Enclosed are:

☒ 19 sheets of drawings.
☐ An assignment of the invention to: _____.
☒ A verified statement to establish small entity status.
☐ _____.

The filing fee has been calculated as shown below:

			Small Entity		Large Entity	
For:	No. Filed	No. Extra	Rate	Fee	Rate	Fee
Basic Fee				$ 345.00		$
Total Claims	2 - 20	0	x $ 9.00	0.00	x $18.00	
Ind. Claims	2 - 3	0	x $39.00	0.00	x $ 78.00	
Mult. Claims			+ $130.00		+ $260.00	
				Total $ 345.00		

☐ Please charge my Deposit Account No. 16-0221 to cover the filing fee and assignment recording fee. A duplicate copy of this sheet is enclosed.

☒ A check in the amount of $345.00 to cover the filing fee ~~(and assignment recording fee)~~ is enclosed.

☒ The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 16-0221. A duplicate copy of this sheet is enclosed.

- ☒ Any additional filing fees required under 37 CFR 1.16.
- ☒ Any patent application processing fees under 37 CFR 1.17.

☒ The Commissioner is hereby authorized to charge payment of the following fees during the pendency of this application or credit any overpayment to **Deposit Account No. 16-0221**. A duplicate copy of this sheet is enclosed.

- ☒ Any patent application processing fees under 37 CFR 1.17.
- ☐ The issue fee set in 37 CFR 1.18 at or before mailing of the Notice of Allowance, pursuant to 37 CFR 1.311(b).
- ☒ Any filing fees under 37 CFR 1.16 for presentation of extra claims.

Respectfully submitted,

Mark Pandiscio 7/7/00

Pandiscio & Pandiscio
470 Totten Pond Road
Waltham, Massachusetts 02451-1914
Tel. (781) 290-0060

MB/SKLAR21.FEE

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Joseph H. Sklar
Title: LIGAMENT SHIM
Attorney's Docket No.: SKLAR-21

Assistant Commissioner For Patents
Washington, D.C. 20231

VERIFIED STATEMENT CLAIMING SMALL BUSINESS ENTITY STATUS - INDEPENDENT INVENTOR

I, Joseph H. Sklar, a citizen of the United States of America residing at 210 Park Drive, Longmeadow, Massachusetts 01106, as the inventor named in the above-identified application, hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for the purposes of paying reduced fees under Title 35, United States Code, Sections 41(a) and (b), to the United States Patent and Trademark Office with regard to the invention described and claimed in the above-identified U.S. Patent Application; that I have not assigned, granted, conveyed or licensed, nor based upon information and belief am I under any obligation under contract or law to assign, grant, license or convey, any rights in said invention to any person who could not likewise be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization as defined in 37 CFR 1.9(d) and (e), respectively.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Title 18, United States Code, Section 1001, and that such willful false statements may jeopardize the validity of the above-identified application, any patent issuing thereon, or any patent to which this verified statement is directed.

Date: 7/7/00

Joseph H. Sklar

MB/SKLAR21.VS

APPLICATION

FOR

UNITED STATES LETTERS PATENT

PATENT APPLICATION

SPECIFICATION

TO ALL WHOM IT MAY CONCERN:

Be it known that Joseph H. Sklar of 210 Park Drive, Longmeadow, Massachusetts 01106 has invented certain improvements in LIGAMENT SHIM of which the following description is a specification.

MB/SKLAR21.CVR

LIGAMENT SHIM

This patent application claims benefit of pending prior U.S. Provisional Patent Application Serial No. 60/143,241, filed 07/09/99 by Joseph H. Sklar for LIGAMENT SHIM, which patent application is incorporated herein by reference.

A ligament is a piece of fibrous tissue which connects one bone to another.

Ligaments are frequently damaged (e.g., detached or torn or ruptured, etc.) as the result of injury and/or accident. A damaged ligament can impede proper motion of a joint and cause pain.

Various procedures have been developed to repair or replace a damaged ligament. The specific procedures used depend on the particular ligament which is to be restored and the extent of the damage.

One ligament which is frequently damaged as the result of injury and/or accident is the anterior cruciate ligament (ACL). The ACL 2 extends between the top of the tibia 4 and the bottom of the femur 6 (Fig. 1). A damaged ACL can cause instability of the knee joint and cause substantial pain and arthritis.

Numerous procedures have been developed to restore the ACL through a graft ligament replacement. In general, these ACL 2 replacement procedures (Fig. 2) involve drilling a bone tunnel 8 through the tibia 4 and up into the femur 6. Then a graft ligament 10, consisting of a harvested or artificial ligament or tendon(s), is passed through the tibial tunnel 12, across the interior of the joint, and up into the femoral tunnel 14. Then a distal portion of the graft ligament is secured in the femoral tunnel 14 and a proximal portion of the graft ligament is secured in the tibial tunnel 12.

There are currently several different ways to secure a graft portion in a bone tunnel. One way is to use an interference screw 16 (Fig. 2) to aggressively wedge the graft ligament against the side wall of the bone tunnel. Another way is to suspend the graft ligament in the bone tunnel with a suture 18 (Fig. 3) or a cross-pin 20 (Fig. 4). Still another way is to pass the graft ligament completely through the bone tunnel and affix the ligament to the outside of the bone with a screw and washer arrangement 22 (Fig. 2) or a staple (not shown).

Depending on the fixation device and its manner of use, some fixation will occur at the portion of the bone tunnel nearest to the interior of the joint, and some fixation will occur intermediate the bone tunnel or adjacent to the portion of the bone tunnel farthest from the interior of the joint. For example, an interference screw 16 set into the femur 6 will typically be positioned substantially adjacent to the interior of the joint 26 (Fig. 5); however, an interference screw 16 set into the tibia 4 will frequently be positioned relatively far from the interior of the joint 26 (Fig. 6). On the other hand, suture 18 (Fig. 3) and cross-pin 20 (Fig. 4) suspensions will typically effect securing intermediate the length of the bone tunnel or at the far end of the bone tunnel, and screw and washer fixations 22 (Fig. 2) will typically effect securing relatively far from the interior of the joint 26.

It has been observed that whenever the graft ligament is secured remote from the interior of the joint 26 (i.e., in the middle of the bone tunnel or adjacent to an outer surface of the bone), the graft ligament 10 will be relatively unsupported at the point

where the ligament 10 passes from the bone tunnel into the interior of the joint. As a result, as the knee flexes back and forth through its natural range of motion (Fig. 7), the graft ligament moves about within the mouth 28 of the bone tunnel, rubbing against the walls of the bone tunnel. Over time, this can cause damage to the graft ligament and the wear down the mouth 28 of the bone tunnel, both to the serious detriment of the patient. It can also result in enlargement of the entire tunnel diameter, e.g., as show at 30. Less than a tight fit may result in incursion of synovial fluid into the tunnel, which is hypothesized to contribute to the tunnel-widening phenomenon.

The solution to this problem is to provide a shim 32 for insertion into the mouth 28 of the bone tunnel (Fig. 8). The shim 32 is formed and sized so as to take up additional space present at the mouth 28 of the bone tunnel and, at the same time, to urge the ligament against the opposing side walls of the bone tunnel. By taking up additional space at the mouth of the bone tunnel, the aforementioned windshield wiper effect can be effectively eliminated. In addition, the entrance

to the bone tunnel will be better sealed against migration of synovial fluid out of the joint and into the bone tunnel. This can be important, since incursion of synovial fluid into the bone tunnel is believed to be deleterious to the ligament reconstruction and to contribute to tunnel widening. At the same time, by urging the graft ligament 10 against the opposing side walls of the bone tunnel 8, osseo-integration between the graft ligament and the host bone will be enhanced. If desired, the shim 32 can be sized and positioned so as to force the ligament 10 against the opposing side walls of the bone tunnel 8 with substantial force so as to enhance attachment of the graft ligament 10 to the bone. However, it should also be appreciated that it is not necessary for the ligament shim 32 to force the ligament against the opposing side walls of the bone tunnel with any great force, since the primary purpose of the shim is simply to occupy excess bone tunnel space, not to compressively secure the ligament to the bone. In other words, the primary purpose of the ligament shim is to form a strategically-placed extension of the bone

tunnel wall, rather than to replace an interference screw.

The ligament shim can take the form of two basic embodiments; a peripheral shim 34 and a centerline shim 36.

The peripheral shim 34 is adapted to fit between the graft ligament 10 and a wall of the bone tunnel (Fig. 9). Thus, the shim effectively provides an extension of the bone wall which it lies against, so as to eliminate the windshield wiper effect discussed above. In one form of the invention, the shim 34 is intended to be held in place through a simple friction fit between the wall of the bone tunnel and the graft ligament. If desired, the shim can be tapered (Figs. 8 and 9) so as to give it a wedge-like configuration and/or the surfaces of the shim can be configured with ribs and/or roughening so as to increase friction with the adjacent anatomy. In another form of the invention, the shim can be suspended by a suture 38 which passes through a shim hole 39 (Fig. 10). Preferably, a shim has at least its outer surface in the shape of an arc (Fig. 11), so that it can conform to the round bone tunnel wall. In one embodiment, the

shim has both its inner and outer surfaces in the shape of an arc 42 (Fig. 11A), so that it can conform to both the round bone tunnel wall and the round graft ligament. If desired, more than one shim can be applied about the periphery of the mouth of the bone tunnel. Alternatively, a single shim can be constructed so that it covers a significant portion of the periphery of the bone tunnel wall.

In some circumstances, the graft ligament consists of single strand of tissue (Fig. 9). In other circumstances, the graft ligament consists of two or more strands 44 of tissue which extend parallel to one another so as to collectively form the graft ligament 10 (Fig. 12). For example, suture and cross-pin suspensions are typically created by looping a long hamstring graft 44 over a suture loop or cross-pin; in this case, there are two graft ligament strands extending parallel to one another in the bone tunnel. The centerline shim 36 is adapted to fit between two such graft ligament strands 44. The centerline shim 36 can be maintained in place through a simple friction fit between the two ligament strands 44 (Fig. 12). Again, the shim can be tapered along its

length so as to give it a wedge-like configuration, and/or the surfaces of the shim can be configured with ribs and/or roughening so as to increase friction with adjacent anatomy. Alternatively, the shim can be suspended by a suture 38 passing through a shim hole 39 (Fig. 13). Preferably, the centerline shim has its two opposing surfaces in the shape of an arc 46, so that the shim can conform to the two round graft ligament strands (Fig. 14). This construction will help keep the centerline shim 36 seated between the ligament strands 44. In some cases, more than two ligament strands 44 might be used in the ligament reconstruction. For example, four ligament strands might be used in the reconstruction. In this case, the shim might comprise four arced surfaces 48 (Fig. 15). Numerous implementations of the centerline shim 36 are contemplated (Fig. 16).

Both the peripheral shim and the centerline shim also provide a benefit beyond simply curing the aforementioned windshield wiper effect. More specifically, at the same time that the shims take up excess room within the bone tunnel, they also urge the graft ligament into engagement with the walls of the

bone tunnel. This urging facilitates osseo-integration between the graft ligament and the host bone, thereby improving surgical results.

In some cases, it may be necessary to redo, or "revise", an earlier ACL reconstruction. This frequently involves forming a new bone tunnel hole adjacent to the old bone tunnel hole. If the old bone tunnel hole 50 occupied a less than ideal position in the host bone 52, it is generally desirable to place the new bone tunnel hole 54 in a better position than the old bone tunnel hole. In some circumstances, the new bone tunnel hole will be placed so close to the old bone tunnel 50 hole that the two will actually overlap (Fig. 17). In this case, there may be a danger of a graft ligament strand 10 "falling" out of the new bone tunnel hole and into the old bone tunnel hole, e.g., as show at 56. With the present invention, a peripheral shim 34 may be used (Fig. 18) so as to close off the new bone tunnel hole 54 from the old bone tunnel hole 50, so as to keep the graft ligament strand from falling into the old bone tunnel hole 50.

It should be appreciated that while the present invention has been discussed above in the context of an

ACL reconstruction, it is not intended to be limited to just ACL reconstructions. The present invention will also find application in other sorts of reconstructions, e.g., other types of ligament reconstructions, etc.

What Is Claimed Is:

1. A ligament shim for insertion into a bone tunnel, the bone tunnel forming a mouth and having at least one ligament extending through the mouth, the at least one ligament and the mouth forming an interstitial space, said ligament shim comprising a body having at least two walls extending in a first direction and defining a cross-sectional area in a second direction, said cross-sectional area conforming to at least a portion of the interstitial space defined by the at least one ligament extending through the mouth, whereby when said shim is placed in said interstitial space between the mouth and the at least one ligament, said shim will hold the at least one ligament against a wall of the bone tunnel.

2. A method for securing at least one ligament to a bone within a bone tunnel, the bone tunnel having a transverse cross-sectional area greater than a transverse cross-sectional area of the ligament, said method comprising:

inserting the at least one ligament into the bone tunnel;

attaching the at least one ligament to the bone; and

inserting said ligament shim into the bone tunnel so as to occupy a portion of the transverse cross-sectional area of said bone tunnel.

Abstract

A shim for placement in a bone tunnel during ligament reconstruction.

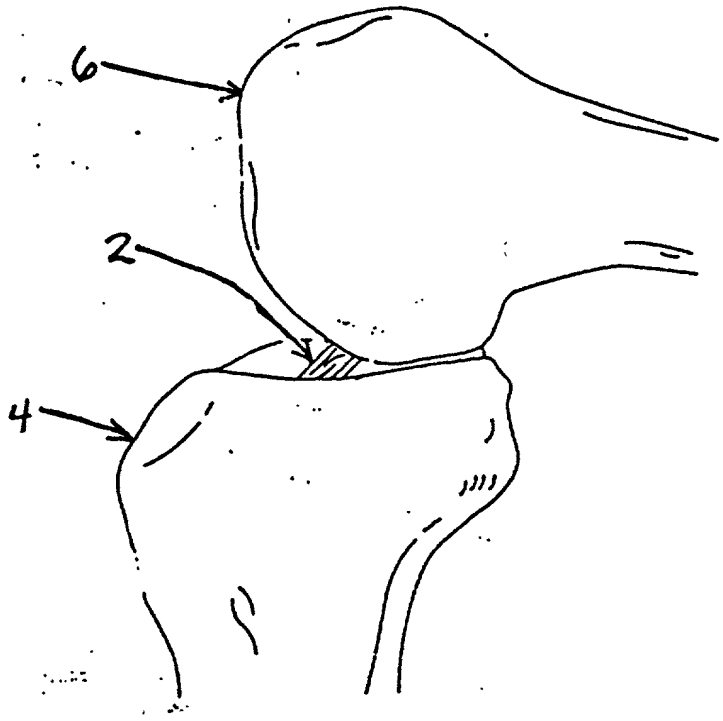


FIG. 1

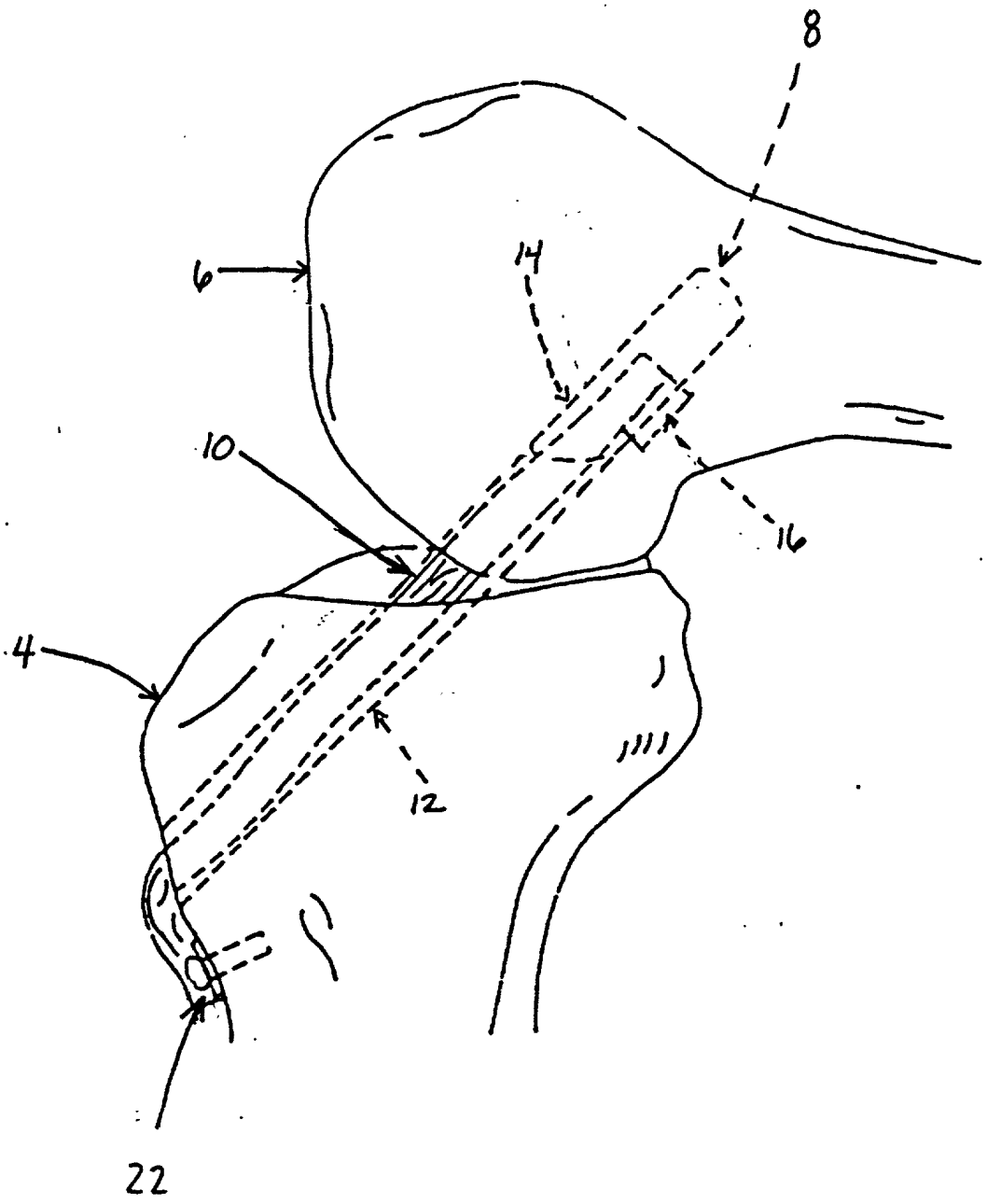


FIG. 2

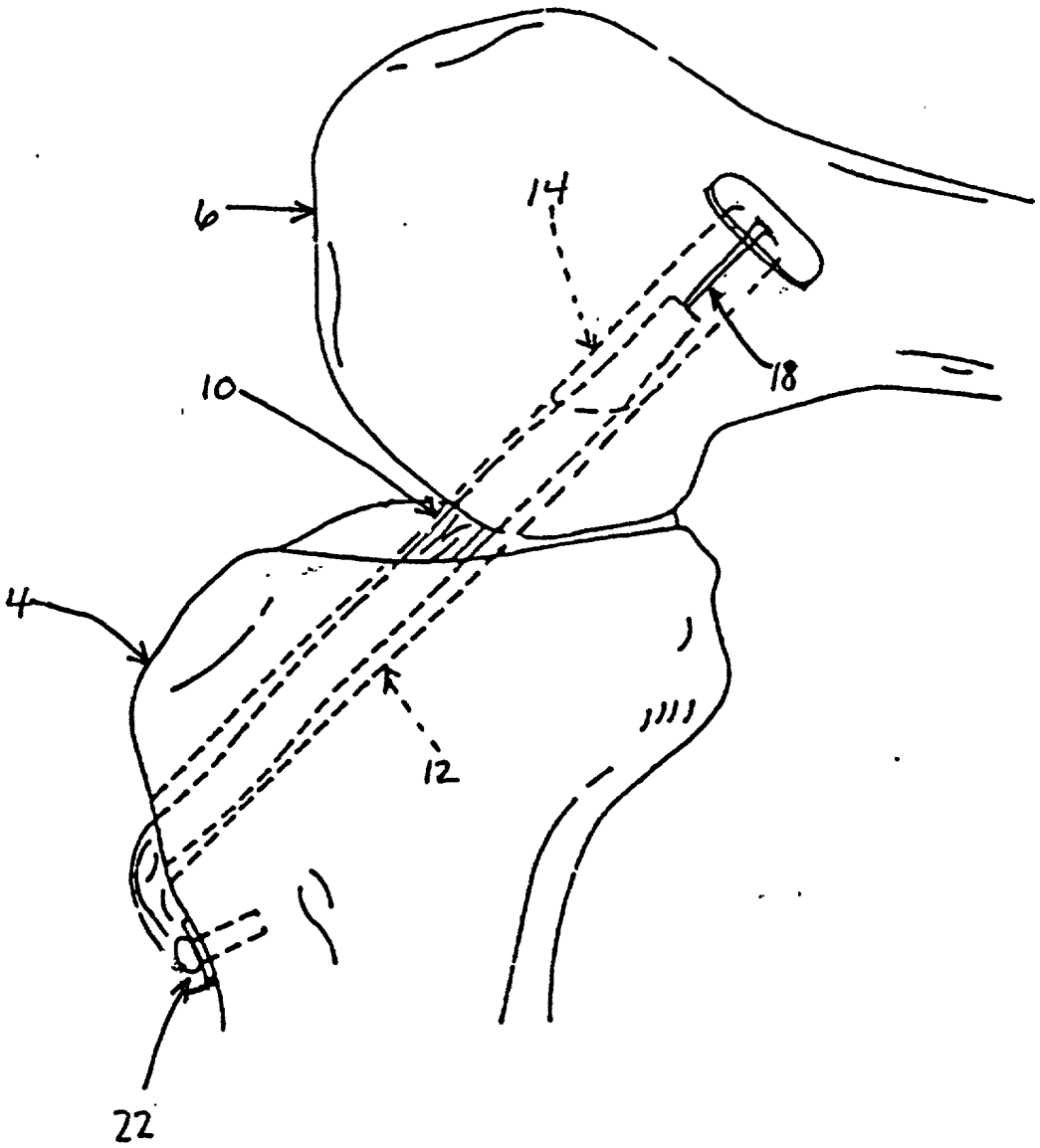


FIG. 3

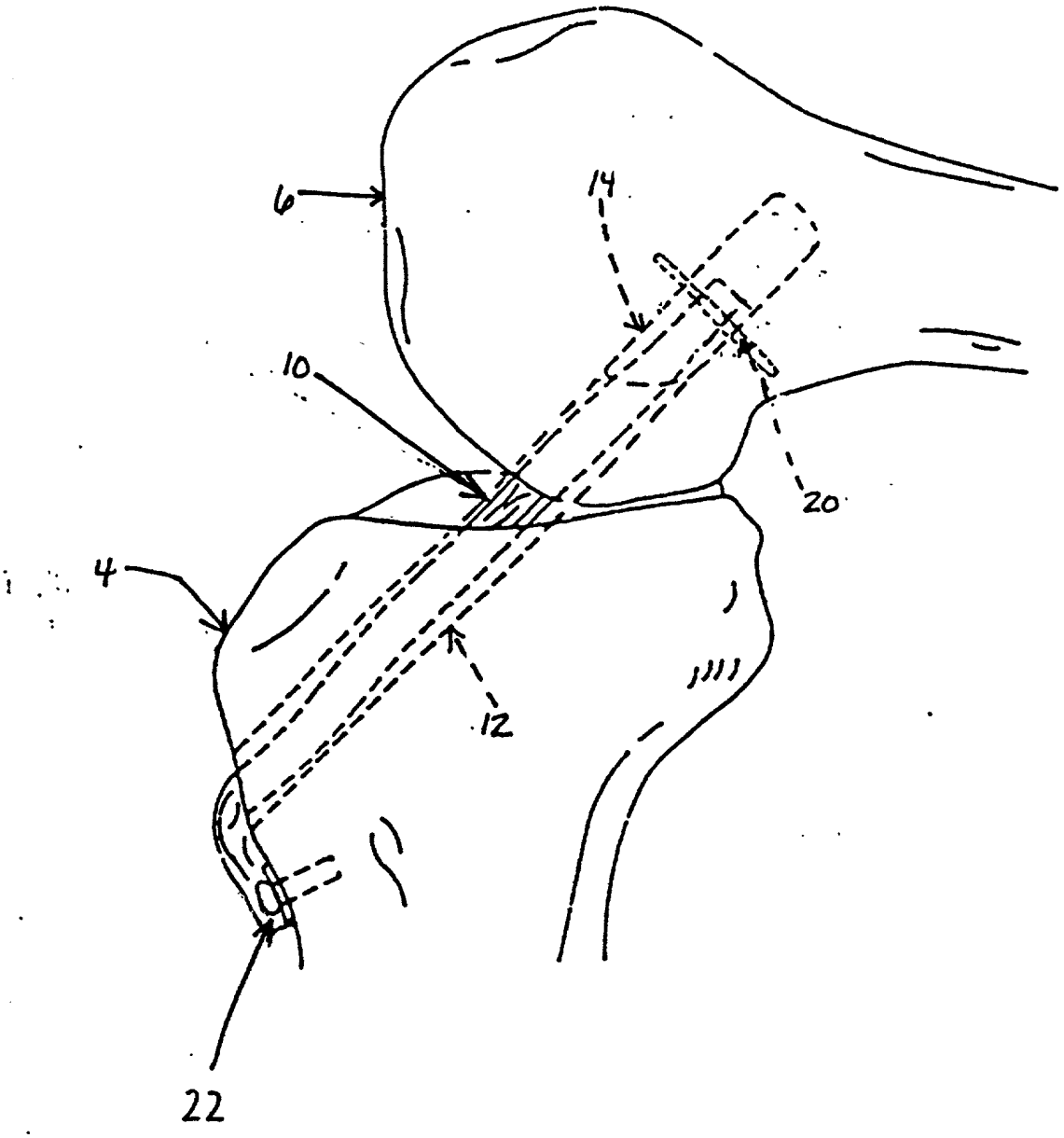


FIG. 4

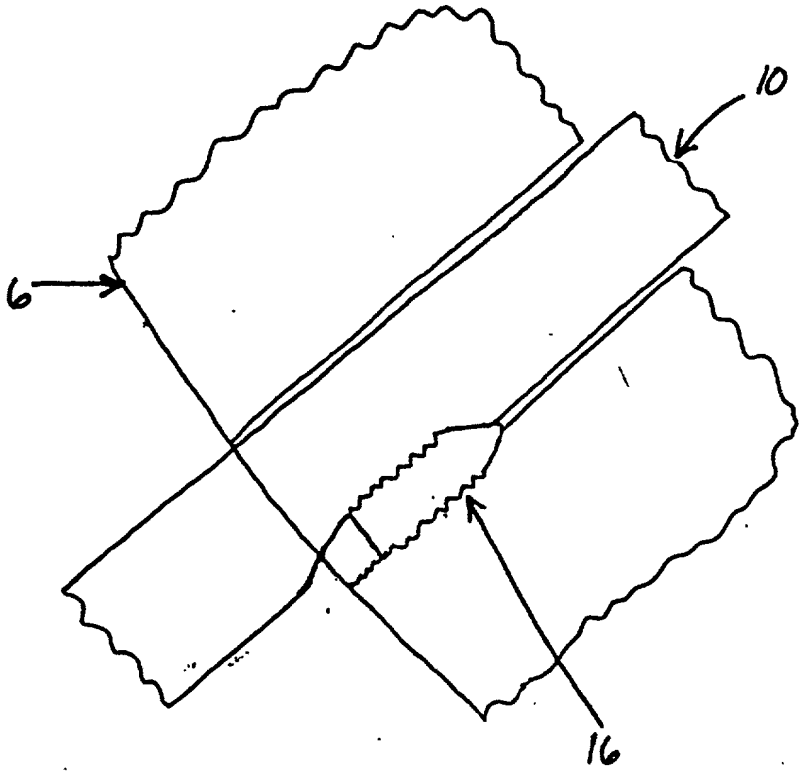


FIG. 5

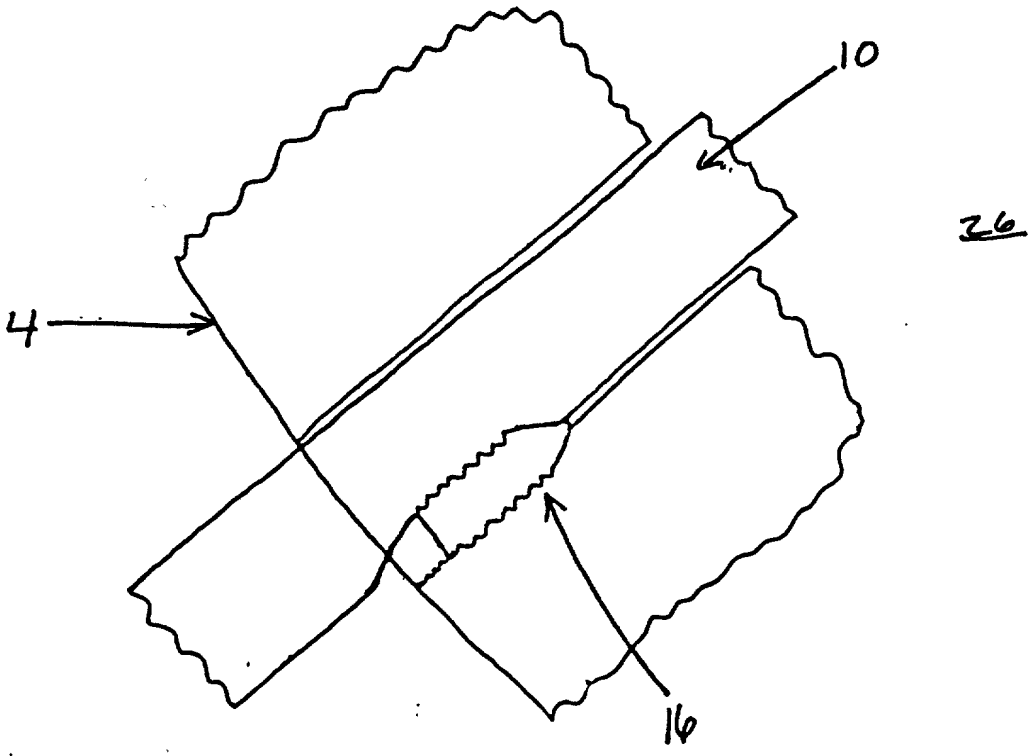


FIG. 6

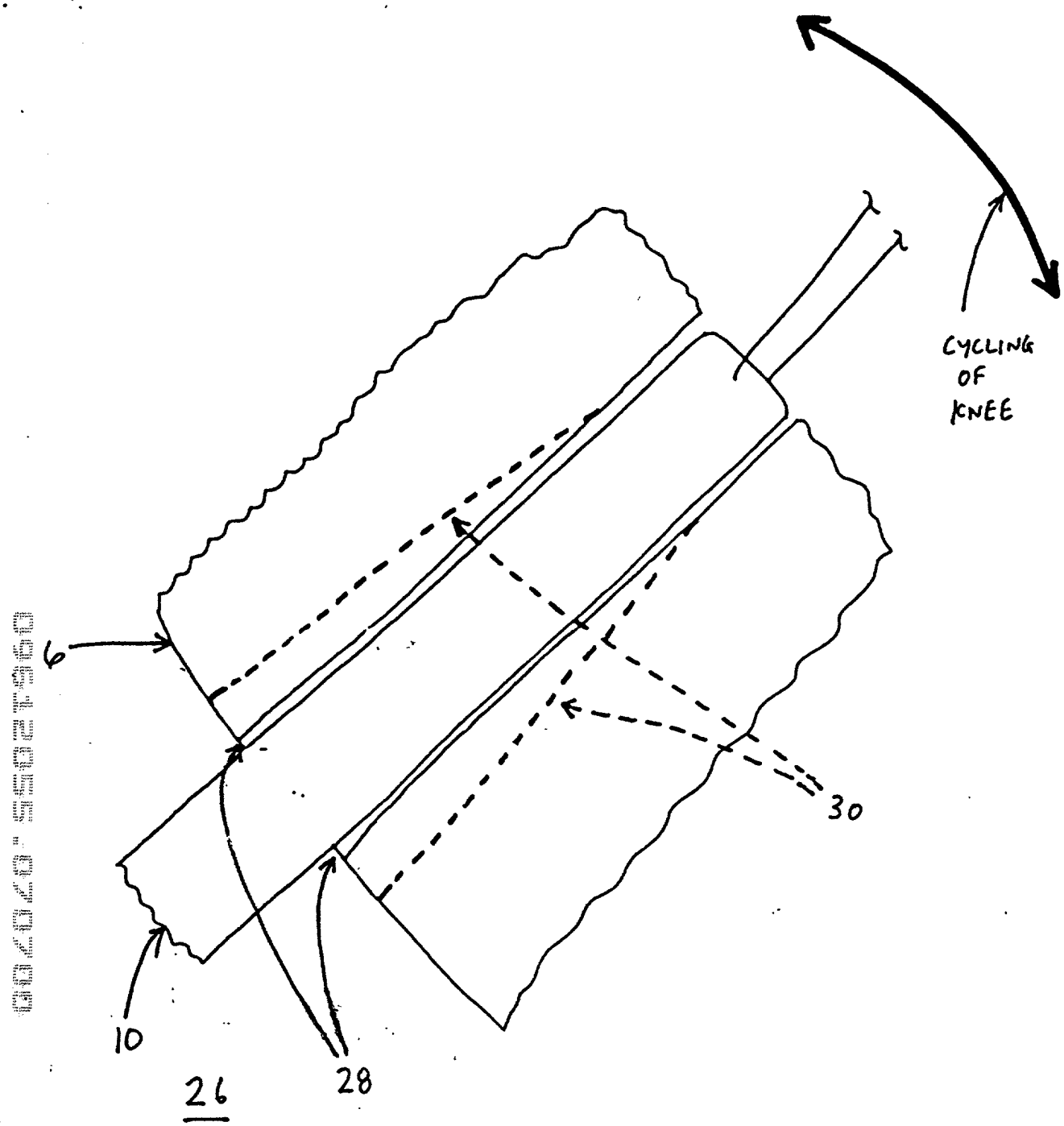


FIG. 7

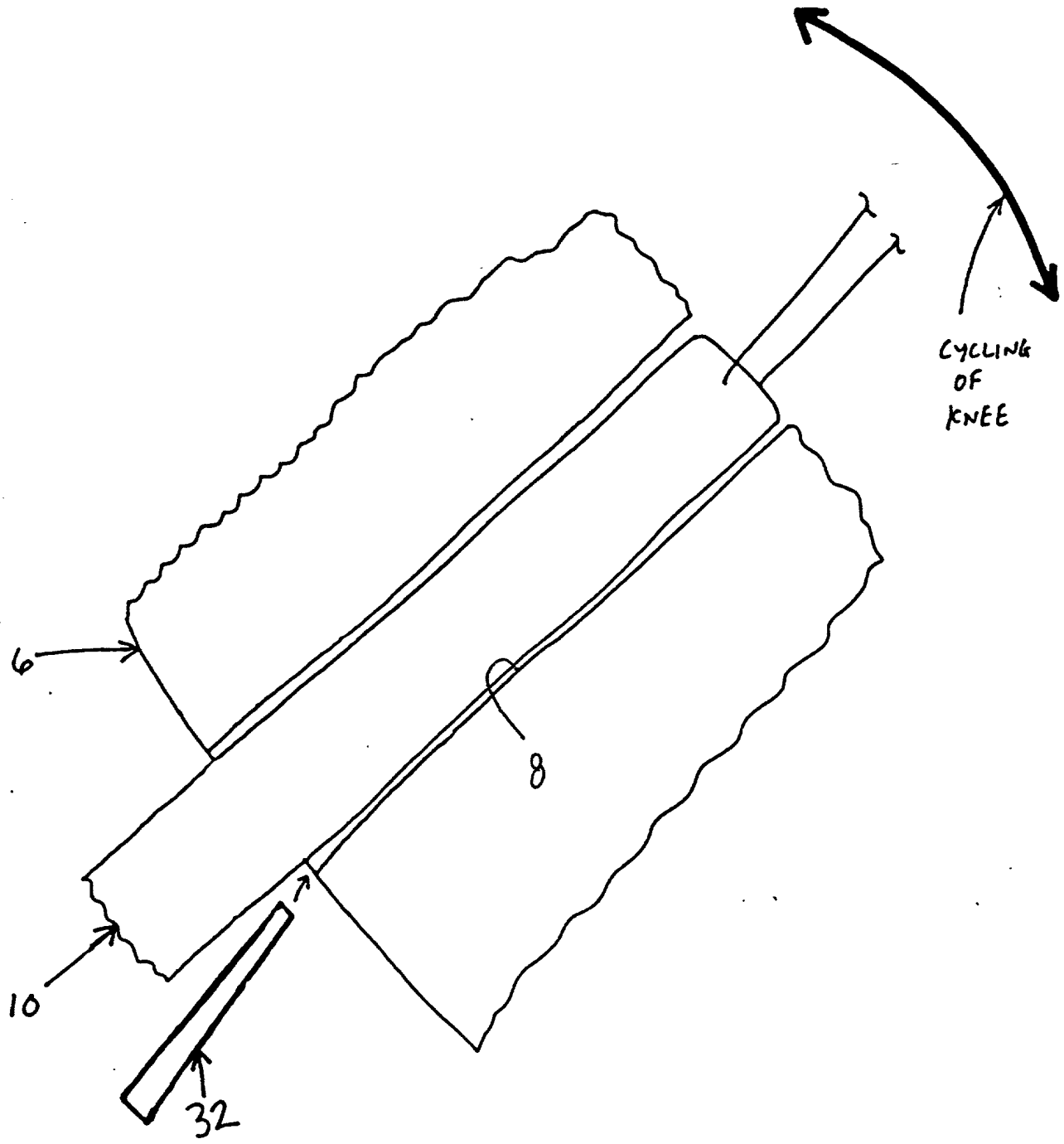


FIG. 8

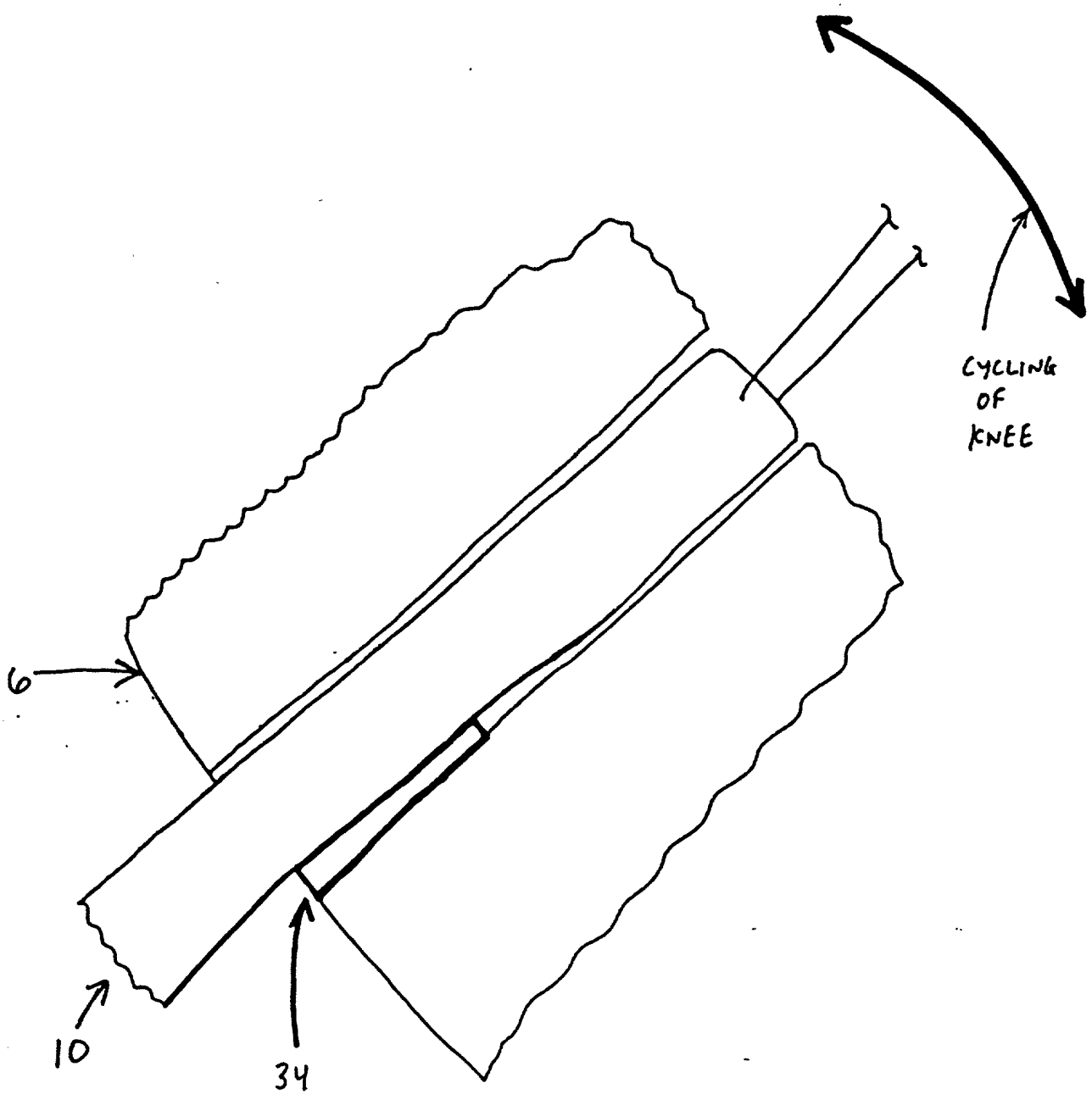


FIG. 9

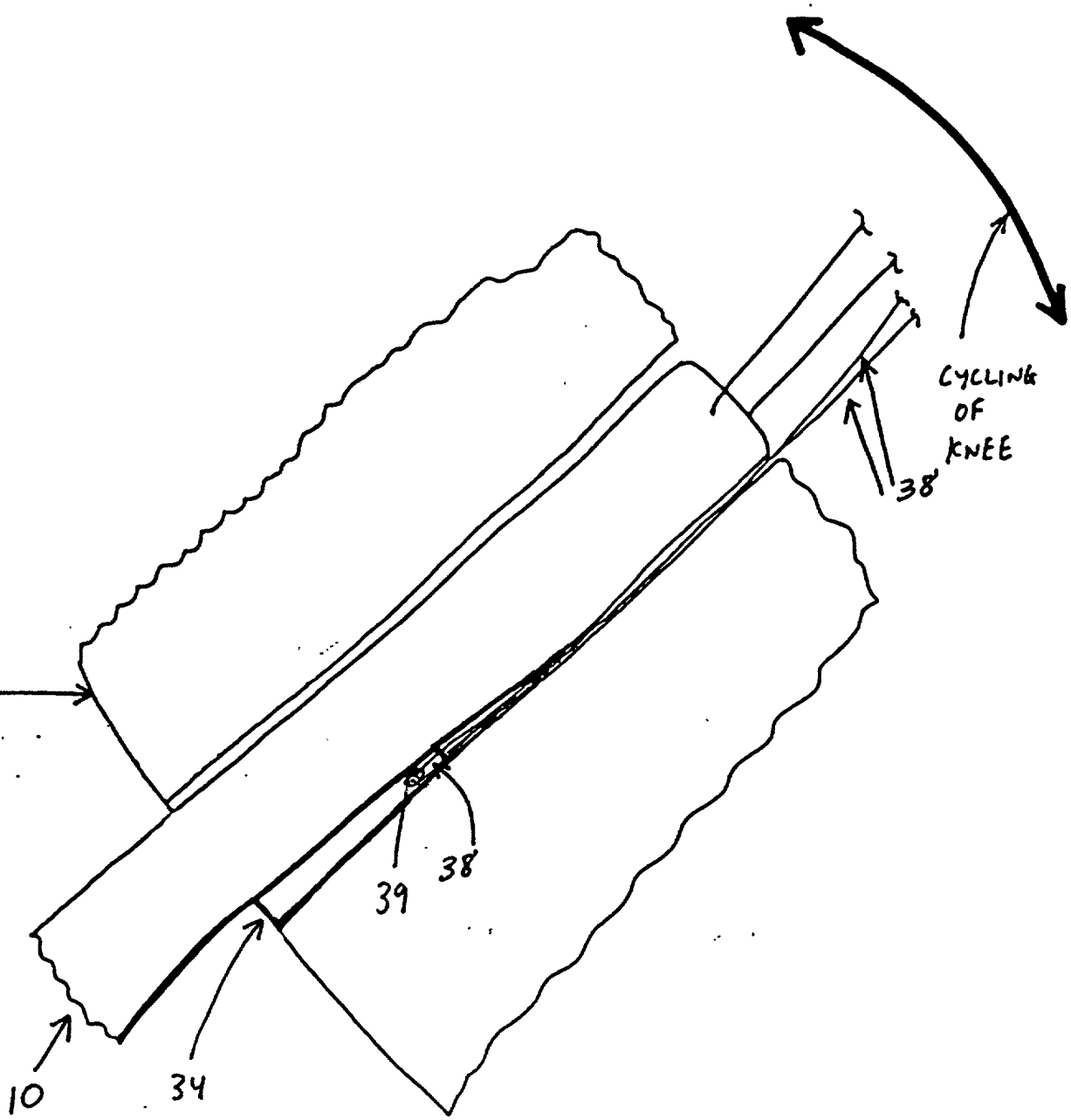


FIG. 10

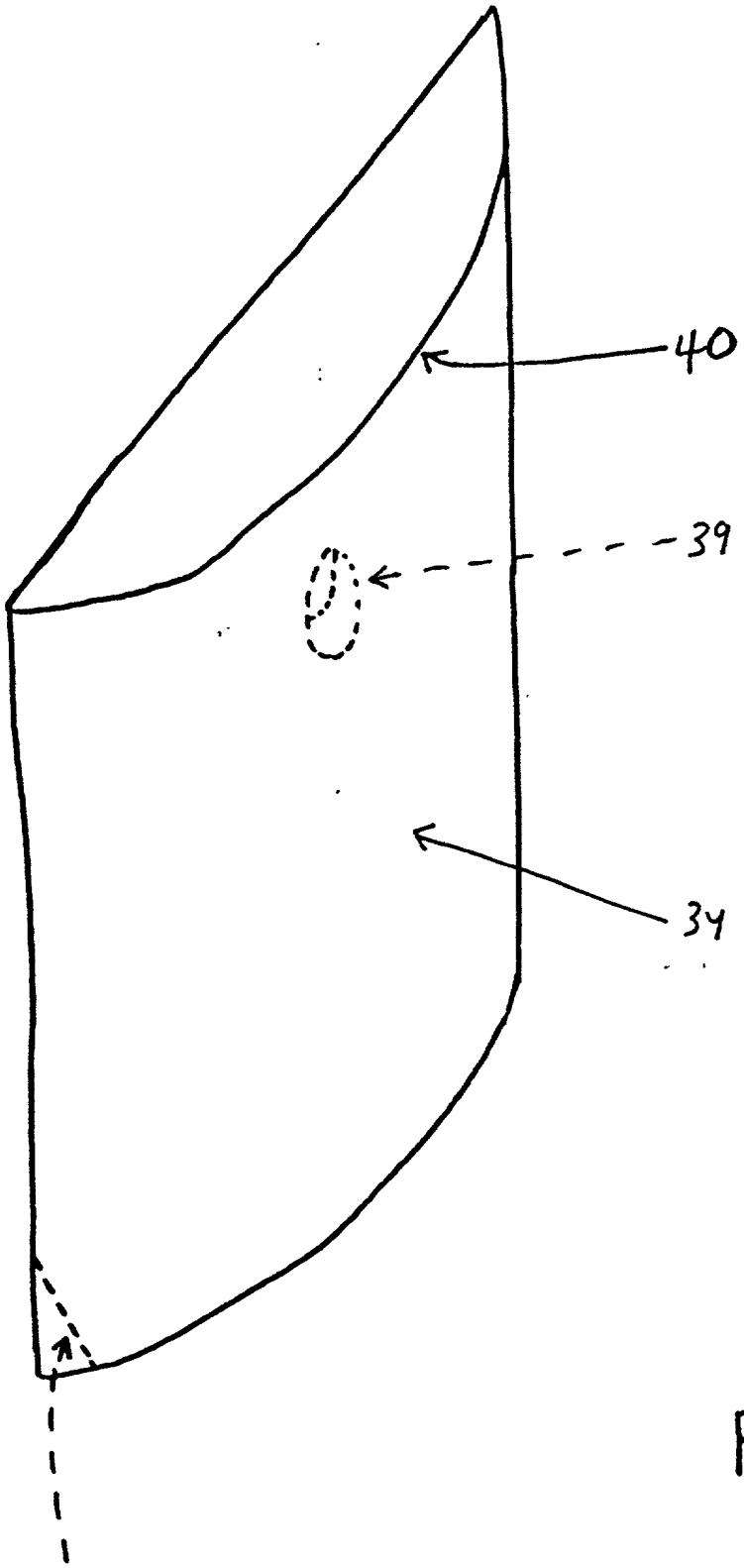


FIG. 11

OPTIONAL: ROUND SURFACES
NEAR MOUTH OF BONE TUNNEL,
TO PROVIDE GENTLE BEARING SURFACES
FOR LIGAMENT

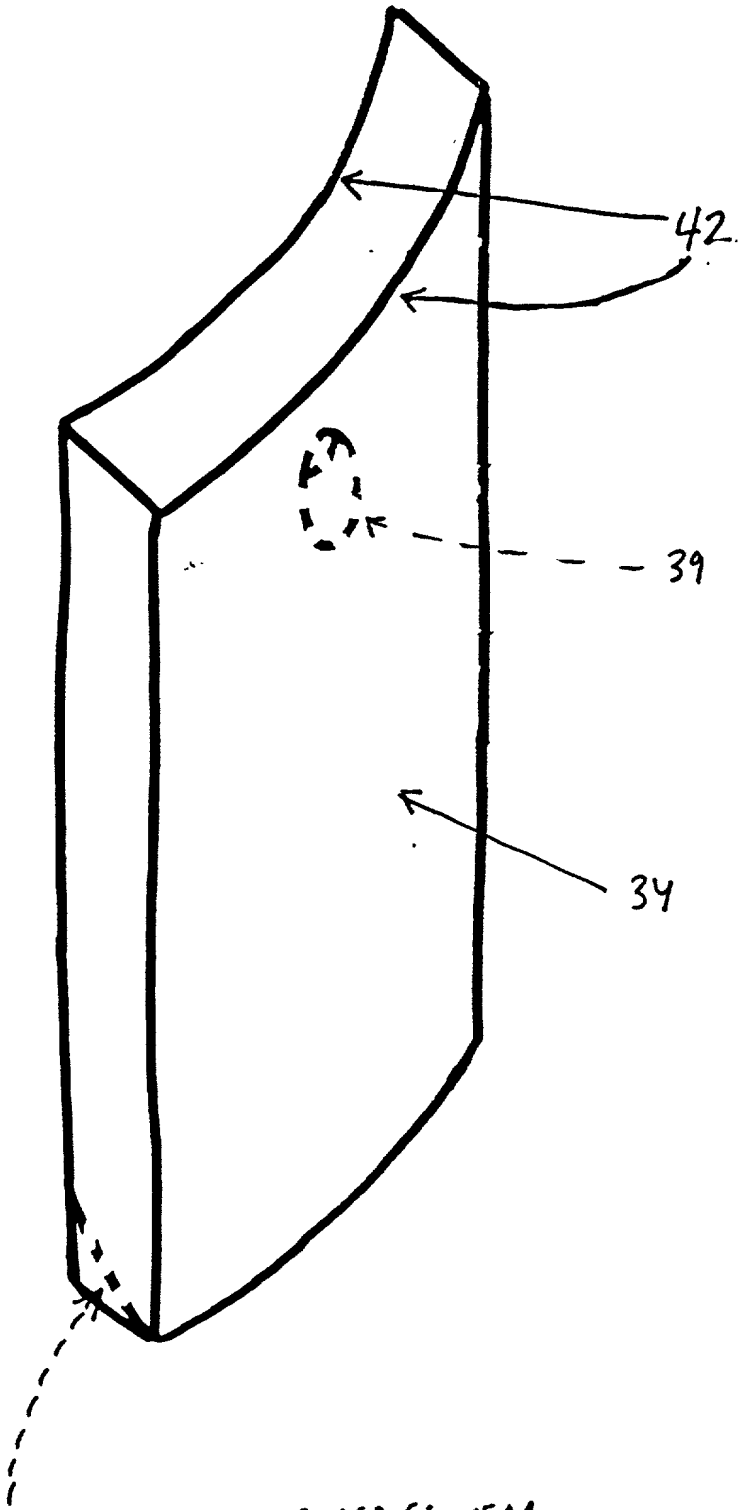


FIG. 11A

OPTIONAL: ROUND SURFACES NEAR MOUTH OF BONE TUNNEL, TO PROVIDE GENTLE BEARING SURFACES FOR LIGAMENT

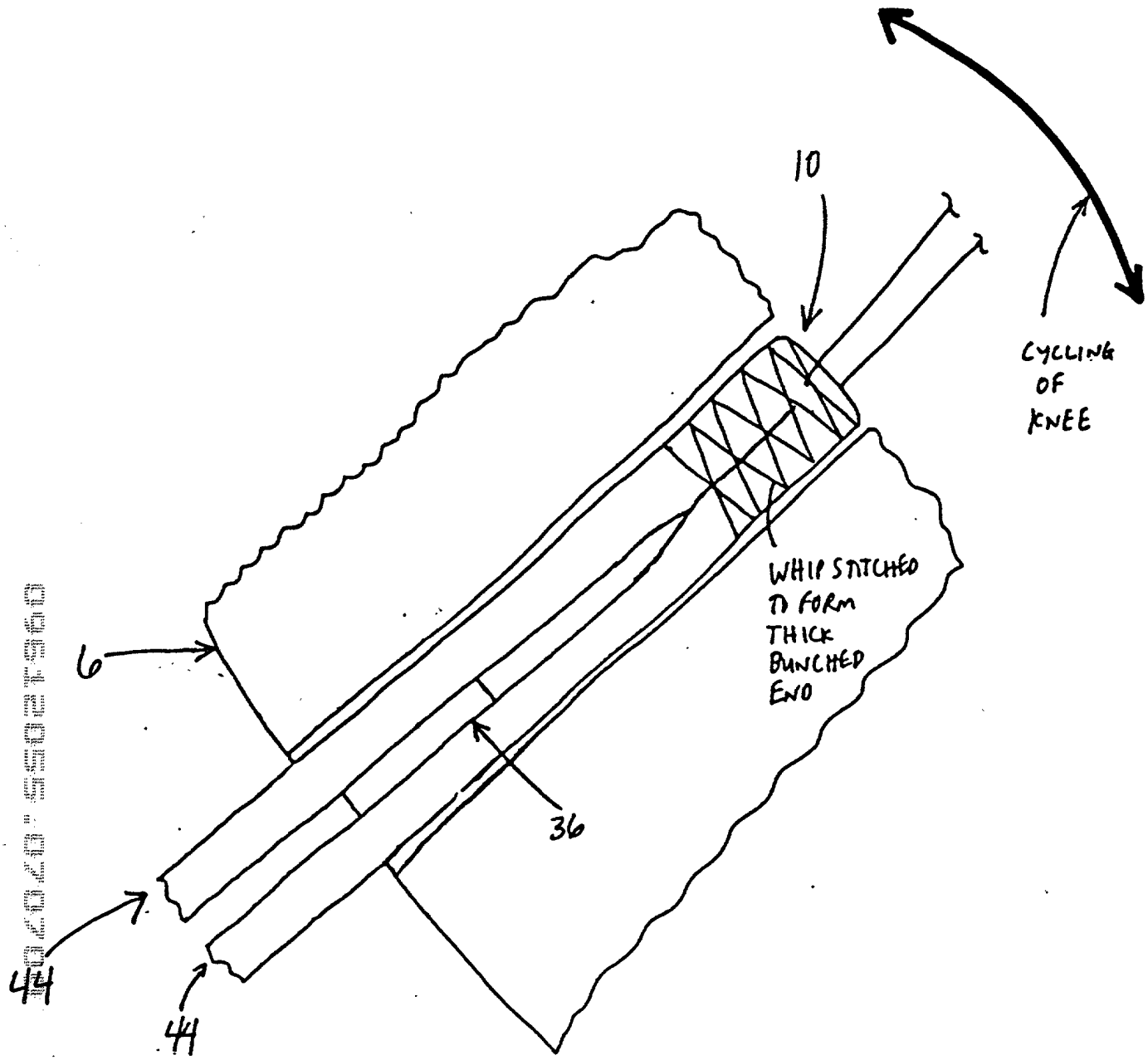

10
CYCLING OF KNEE
WHIP STITCHED TO FORM THICK BUNCHED END
6
36
44
44

FIG. 12

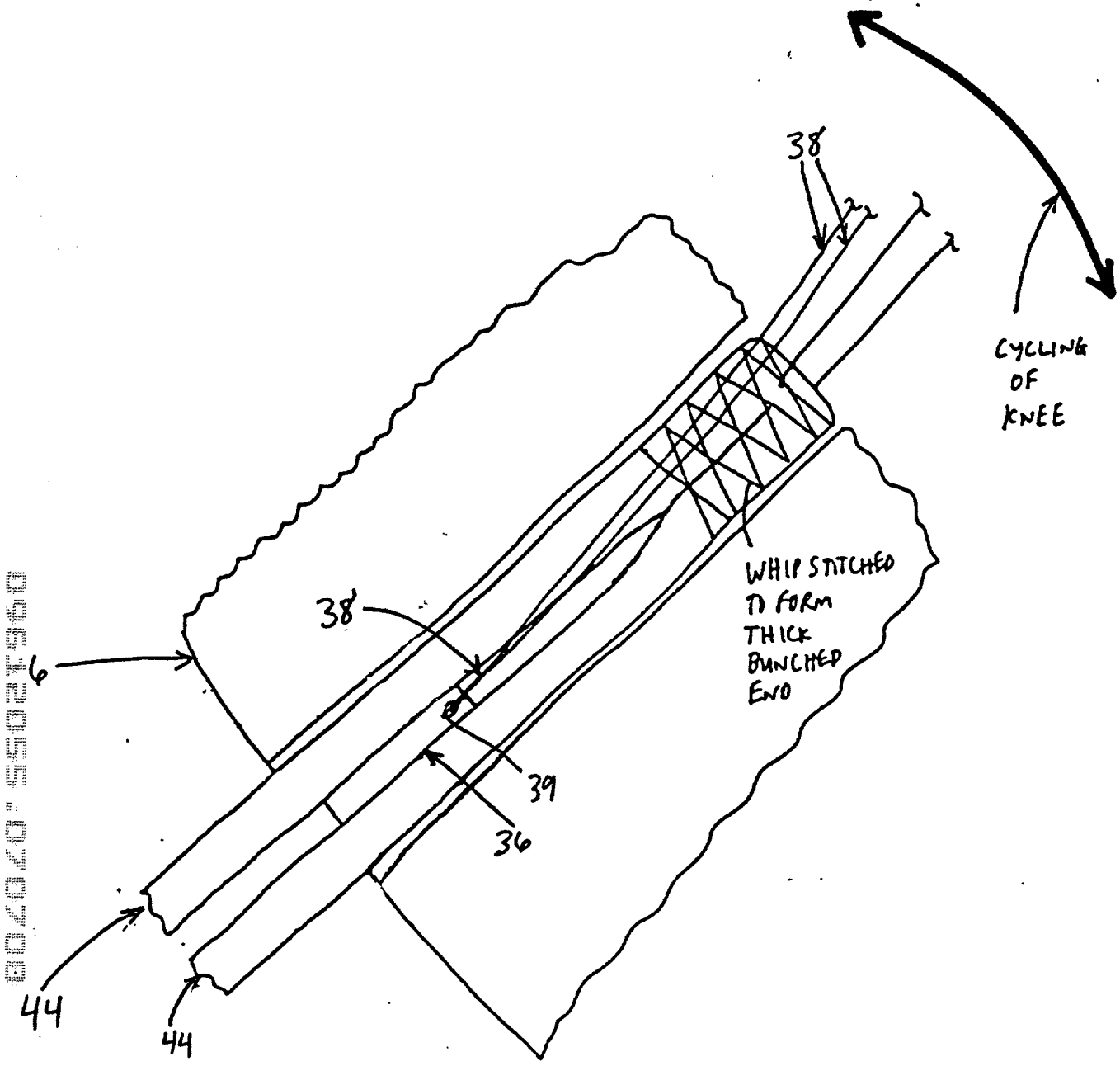

38
CYCLING OF KNEE
WHIP STITCHED TO FORM THICK BUNCHED END
38
6
39
36
44
44

FIG. 13

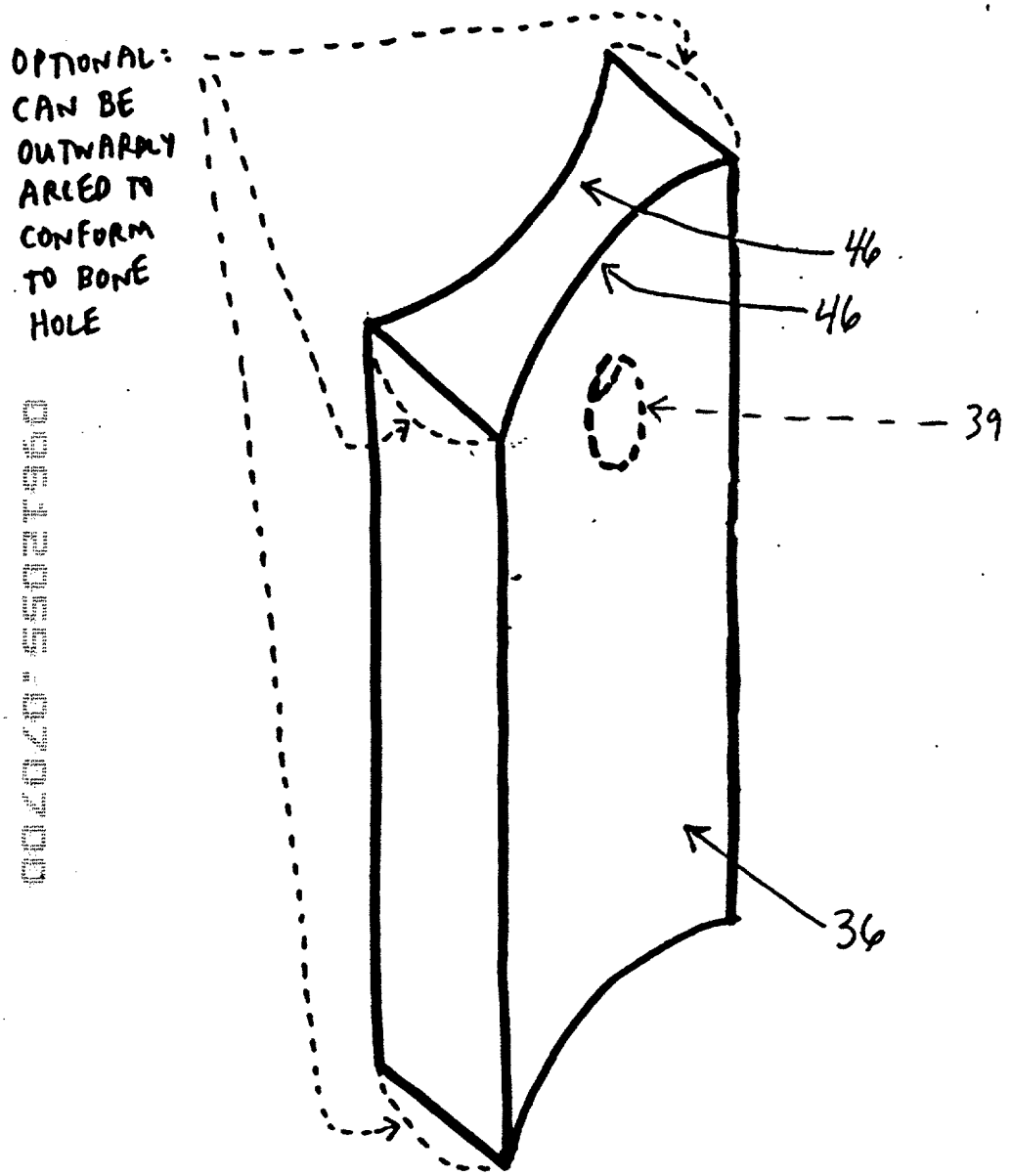

OPTIONAL: CAN BE OUTWARDLY ARCED TO CONFORM TO BONE HOLE
46
46
39
36

FIG. 14

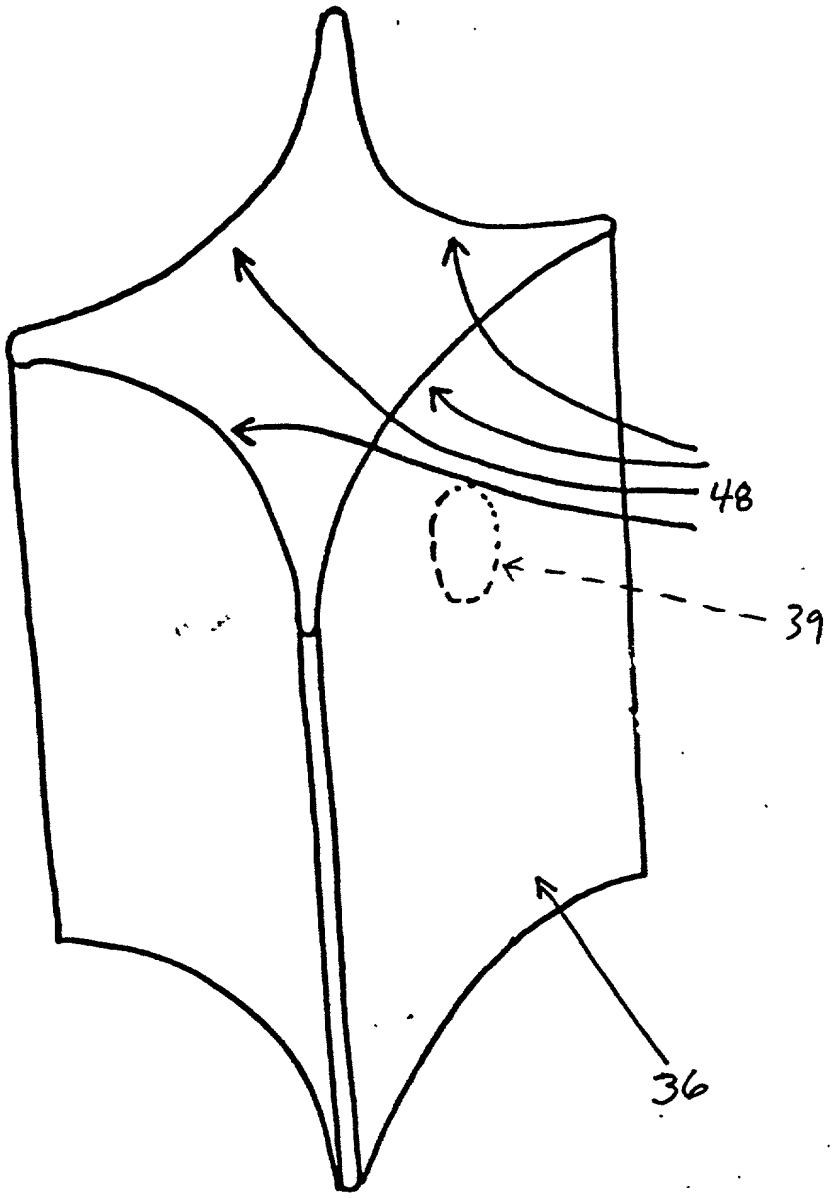


FIG. 15

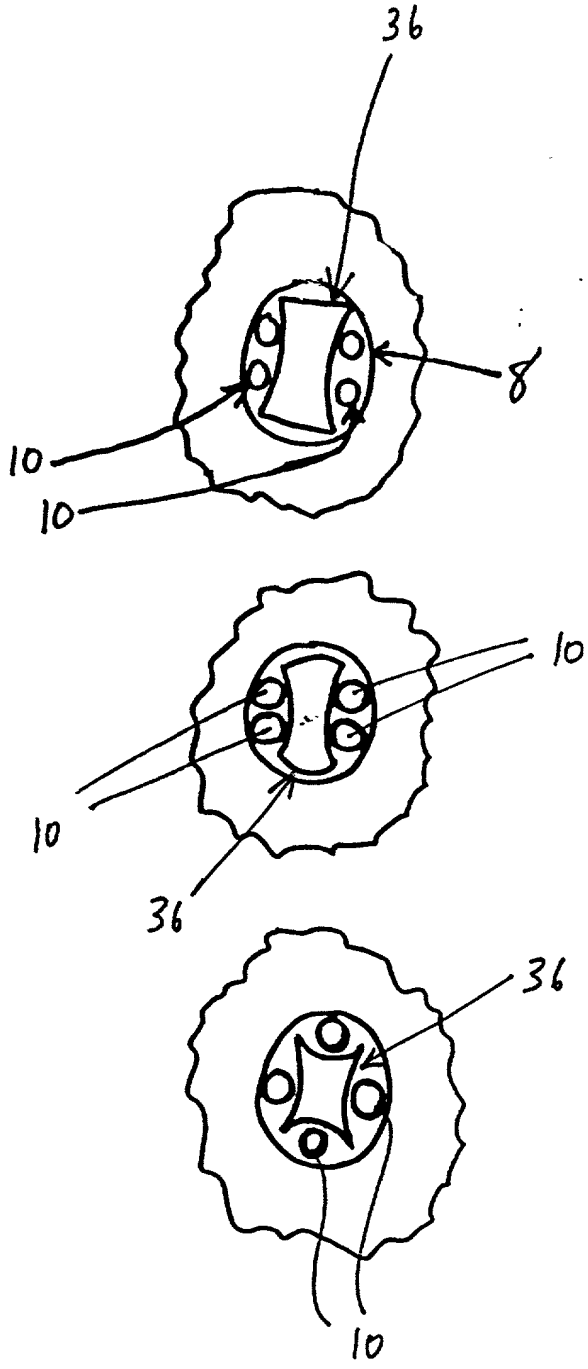


FIG. 16

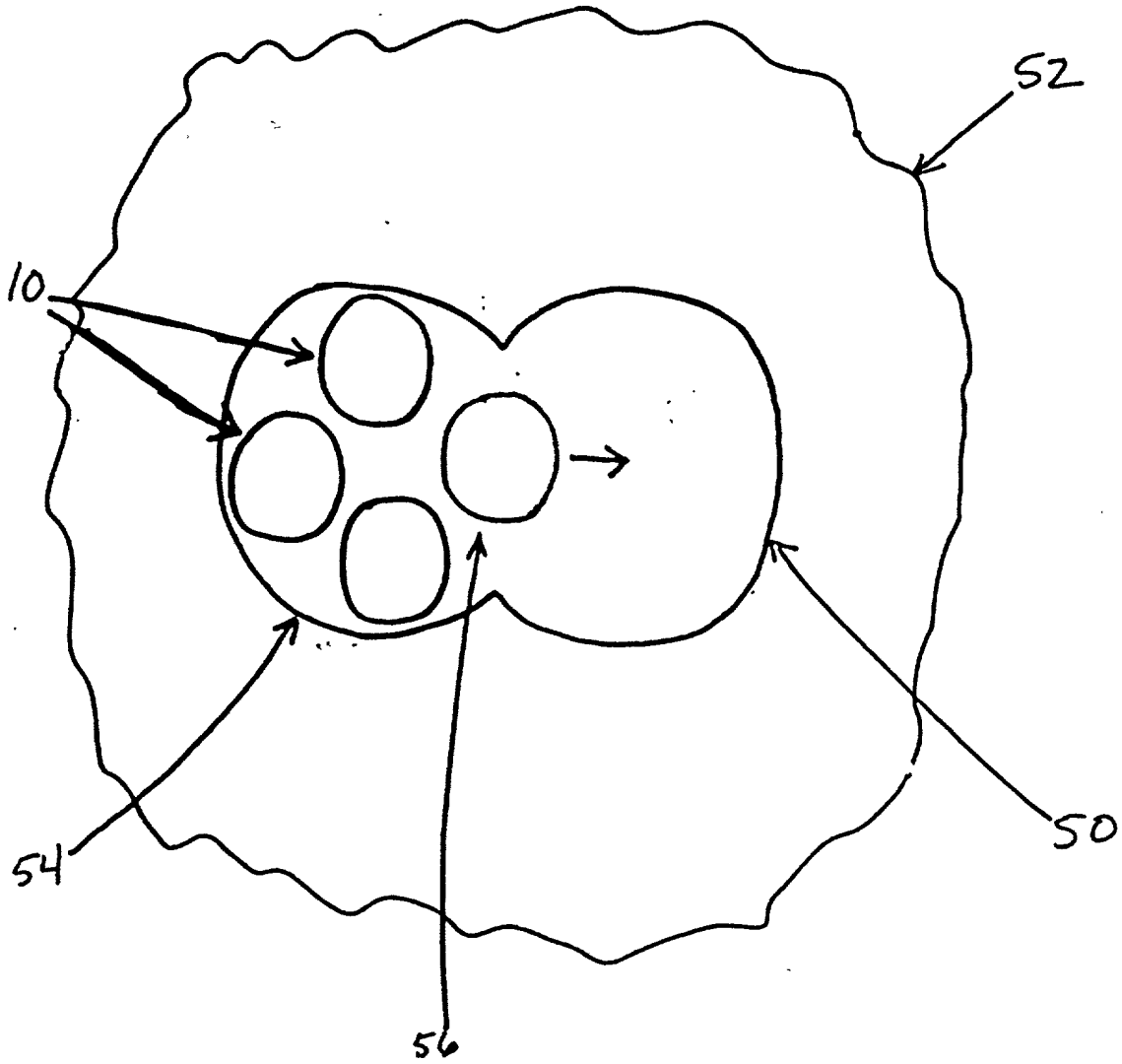


FIG. 17

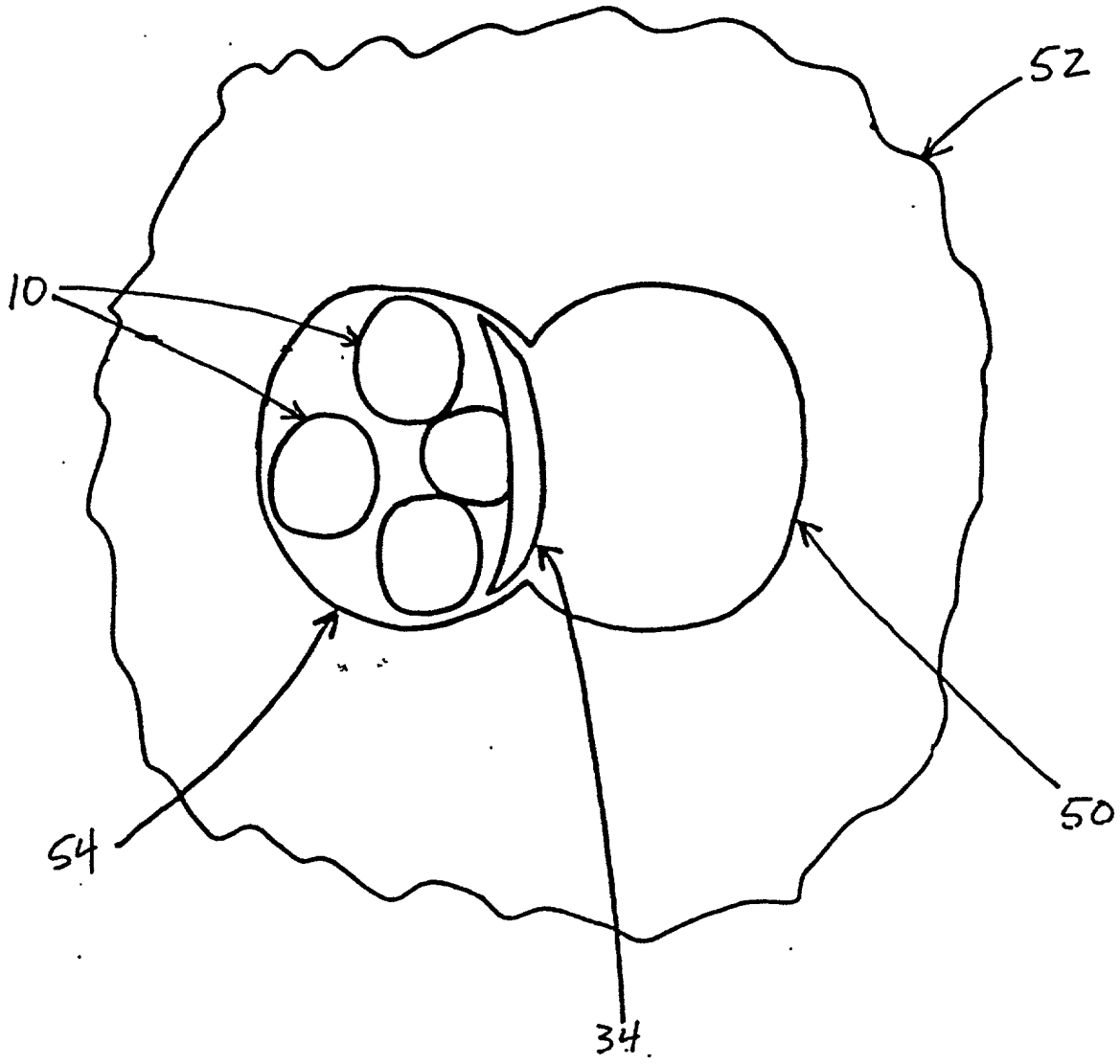


FIG. 18

DECLARATION AND POWER OF ATTORNEY

As a below-named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled "LIGAMENT SHIM", the specification of which is attached hereto and is identified by Attorney's Docket No. SKLAR-21.

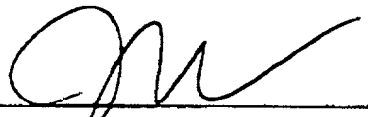
I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

I hereby claim priority benefits under Title 35, United States Code, Section 119(e), of U.S. Provisional Patent Application Serial No. 60/143,241, filed 07/09/99 for LIGAMENT SHIM.

I hereby appoint Pandiscio & Pandiscio, a firm composed of Nicholas A. Pandiscio, Registration No. 17293, Mark J. Pandiscio, Registration No. 30883, Scott R. Foster, Registration No. 20570, and James A. Sheridan, Registration No. 43,114 or any of them, of 470 Totten Pond Road, Waltham, Massachusetts 02451-1914, (Telephone No. 781-290-0060), my attorneys with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent Office connected therewith.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Inventor's signature: 

Inventor's full name: Joseph H. Sklar

Date: 7/7/00

Residence: 210 Park Drive
Longmeadow, Massachusetts 01106

Post office address: same

Citizenship: United States of America

MB\SKLAR21.AP2